

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

MAXXIM CARE EMS, INC., §
Plaintiff, §
§
vs. § CIVIL ACTION H-10-1408
§
§
KATHLEEN SEBELIUS, SECRETARY OF §
UNITED STATES DEPARTMENT OF §
HEALTH AND HUMAN SERVICES, §
Defendant. §

SUMMARY JUDGMENT OPINION

Pursuant to 42 U.S.C. § 1395ff(b), Maxxim Care EMS, Inc. seeks judicial review of the Secretary's final decision that the Medicare program overpaid Maxxim for ambulance services. Maxxim and the Secretary have filed cross-motions for summary judgment. The Secretary's motion (Dkt. 27) is granted and Maxxim's (Dkt. 20) is denied.¹

Background

The following facts are undisputed. Maxxim is an ambulance company that primarily provides transport to Medicare beneficiaries to and from hemodialysis. A Medicare program safeguard contractor (PSC), TriCenturion, performed a post-payment audit of Maxxim's claims from August 2003 - Sept. 2006. TriCenturion

¹ The parties have consented to magistrate judge jurisdiction for all purposes, including entry of judgment (Dkt. 35).

reviewed 30 sample claims (for 17 beneficiaries), found a 100% error rate, and extrapolated the error rate over 3,941 claims.² In June 2007, TrailBlazer Health Enterprises, L.L.C., a contractor for the Center for Medicare and Medicaid Services (CMS), notified Maxxim that it owed Medicare \$1,051,325.92. TrailBlazer upheld the overpayment on redetermination, and a qualified independent contractor (QIC), in this case Q2 Administrators, denied Maxxim's request for reconsideration. Maxxim appealed the QIC decision and was granted a hearing before a Medicare administrative law judge. The ALJ issued a ruling in September 2009 that (1) 25 of the 30 reviewed claims were not covered and were properly denied; and (2) the sampling performed by TriCenturion was not "sufficiently reliable to withstand scrutiny under a due process analysis."³ Maxxim did not seek review of the ALJ decision. However, on November 20, 2009, the QIC (on behalf of CMS) referred the case to the Medicare Appeals Counsel (MAC) for review urging that the ALJ erred in setting aside the extrapolation on the basis of due process and that the ALJ erred in finding the sampling unreliable.

In a February 25, 2010 ruling, the MAC reversed the ALJ decision that the sampling was unreliable, finding that any due process concerns were addressed by

² In 2009, Health Integrity, LLC took over the investigative function from TriCenturion as Zone Program Integrity Contractor (ZPIC).

³ Dkt. 1-2, at 22-23.

Maxxim's opportunity to review and comment on the PSC's sampling methodology.

The MAC decision is the final agency decision.

On April 27, 2010, Maxxim filed this case for judicial review of the final agency decision, asserting a violation of due process.

Analysis

The court reviews the final decision of the Secretary pursuant to Medicare Act § 205(g) to determine (1) whether the proper legal standards were applied; and (2) whether the decision is supported by substantial evidence on the record as a whole.

Estate of Morris v. Shalala, 207 F.3d 744, 745 (5th Cir. 2001). Substantial evidence is “such relevant evidence as a reasonable mind might accept to support a conclusion.” *Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 215 (5th Cir. 1996). Courts are to give substantial deference to an agency's interpretation of its own regulations. *Sta-Home Health Agency, Inc. v. Shalala*, 34 F.3d 305, 308 (5th Cir. 1994).

The court reviews *de novo* Maxxim's due process claim under the 5th Amendment and its request for declaratory judgment. *See Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 23 (2000).

A. Exhaustion

As a threshold matter, the court must determine whether Maxxim exhausted its

administrative remedies before seeking judicial review. There is no dispute it did so as to its claim regarding the invalidity of the extrapolation. However, the Secretary argues that this court lacks jurisdiction to review coverage of the 25 sample claims denied by the ALJ because Maxxim did not exhaust the issue before the MAC.

Under the Medicare Act, a party dissatisfied with a contractor's overpayment calculation must go through four levels of administrative review before seeking judicial review: (1) redetermination; (2) reconsideration; (3) Administrative Law Judge hearing; and (4) MAC review. In other words, a claimant must exhaust its administrative remedies. *Rencare, Ltd. v. Humana Health Plan of Texas, Inc.*, 395 F.3d 555, 557 (5th Cir. 2004); 42 C.F.R. § 405.1136.

There are two ways for an ALJ decision to reach MAC review. A party may request review pursuant to 42 C.F.R. § 405.1100, or the MAC may take up the appeal by its own motion pursuant to 42 C.F.R. § 405.1110(a). In the later situation:

If CMS or its contractor participated in an appeal at the ALJ level, the MAC exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

42 C.F.R. § 405.1110(c).

CMS raised only one exception to the ALJ decision for MAC review. As stated in the MAC's February 25, 2010 decision: "CMS did not seek Council review of the ALJ's findings regarding Medicare coverage of the sampled claims at issue; therefore, we do not disturb the ALJ's findings on the coverage of the sampled claims or the appellant's liability for those overpayments."⁴

The record is clear that Maxxim did not exhaust its administrative remedies regarding coverage of the 25 denied claims affirmed by the ALJ. The Secretary is entitled to summary judgment on that claim.

B. The MAC Decision

Chapter 3 of the Medicare Program Integrity Manual (PIM) sets guidelines for the use of statistical sampling and extrapolation in the calculation of Medicare overpayments. The Secretary summarized the guidelines in its 2010 final decision.⁵ The MAC concluded that the ALJ erred in finding that the overpayment demand violated due process. Maxxim contends that the MAC decision upholding the validity of the extrapolation methodology is not supported by substantial evidence.

Three experts testified at the ALJ hearing regarding the statistical validity of the sampling and extrapolation. Dr. Williams, the Secretary's independent expert,

⁴ Dkt. 13, at 4.

⁵ *Id.* at 8-14.

testified that a program called RANUNI was used to generate the sample of 30 claims from all claims paid in the audit period. The methodology for determining the extrapolated overpayment is called the “Minimum Sum Method,” and was developed by Dr. Don Edwards.

Williams looked at the universe of 3,941 claims and examined the parameters of PIM Chapter 3, § 3.10.4.4. He determined that the documentation provided by the PSC was inadequate to support the sample and that the sample was not representative. For example, only two beneficiaries made up almost half of the claims. He opined that the sample should not be used to extrapolate an overpayment amount. After the PSC provided additional documentation post-hearing, Williams prepared a supplemental report confirming that his opinion was unchanged.

Maxxim presented Dr. Will Yancey, a former president of Maxxim, as its expert. Yancy testified that the 30-claim sample was not representative of the universe. He noted that there was no record of the assumptions the PSC made about the universe of claims in creating its sample. Neither he nor Dr. Williams could recreate the sample using the documentation provided, as is required by PIM § 3.10.4.4.1. He further noted that the over-representation of a particular patient (the 30 claims related to 17 individual patients) could skew the sample. For these reasons, he opined that the PSC did not perform proper statistical sampling and extrapolation.

Health Integrity (the ZPIC who took over from the PSC, TriCenturion) presented Dr. Dobbins as its expert. Dobbins opined that the PSC maintained accurate documentation and followed proper procedures. He noted that the only assumptions underlying the PSC's methodology were that the sample was randomly selected, and that all the payments were either totally in error or totally correct. Dobbins refuted Yancey's and William's opinion that the sample must be representative of the universe, and opined the sample need only be truly random to be proper.

Maxxim had the burden to prove the invalidity of the statistical sampling and extrapolation. The MAC found error in the ALJ's ruling that the PSC's methodology raised due process concerns because the ALJ erroneously placed the burden of proving the validity of the sampling on the PSC.⁶ Failure to follow PIM guidelines is not a basis for setting aside a statistical sample or extrapolation: "An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and collected." PIM, § 3.10.1.1. Moreover, "[a] challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved

⁶ See Dkt. 13, at 15-16.

in the sample design.” PIM, § 3.10.4.3.

Maxxim's evidence of record showed a basis for criticizing the PSC's sampling methodology. However, Maxxim “failed to offer any affirmative evidence demonstrating that TriCenturion's sampling methodology did not comport with the guidelines established by CMS Ruling 86-1 and the MPIM.”⁷ Given the deferential standard of review this court is bound to apply, the court finds that the MAC's decision is supported by substantial evidence in the record.

C. 5th Amendment Due Process

The Due Process Clause of the 5th Amendment provides that “No person shall be deprived of life, liberty, or property, without due process of law.” The Due Process Clause encompasses substantive and procedural components. Procedural due process ensures that government action that deprives a person of life, liberty, or property, is implemented in a fair manner. Substantive due process protects against arbitrary or capricious government action that shocks the conscience. *U.S. v. Salerno*, 481 U.S. 739, 746 (1987). Maxxim claims violations of its procedural and substantive due process rights under the 5th Amendment.

The Secretary determined that the opportunity to review and comment upon the PSC's sampling information resolved any due process concerns and argues that there

⁷ *Id.* at 16.

is no basis for this court to reverse that determination. The court agrees. Maxxim has shown no lack of procedural due process in this case.⁸

In addition, Maxxim has not shown any basis for a substantive due process claim. Maxxim has presented no authority for its assertion that the Secretary's failure to follow the PIM guidelines constitutes a *per se* deprivation of a substantive due process right. Maxxim cites *Kindred v. Spears*, 894 F.2d 1477 (5th Cir. 1990) for the proposition that when the government binds itself by mandatory rules, the failure to follow such rules violates the aggrieved party's substantive due process rights. *Kindred* addressed the Parole Commission's calculation of the time Kindred would serve on parole, arguably implicating a greater fundamental right than Maxxim has established here. But more significant, the PIM is not a set of mandatory regulations. See 42 C.F.R. §405.1062(a) ("ALS and the MAC are not bound by . . . program memoranda and manual instructions, but will give substantial deference . . ."). As pointed out by the MAC, the PIM expressly provides that a mere failure to follow its provisions is not a basis for challenging the sample, and the burden is on the claimant to show affirmatively that the methodology resulted in error.

In sum, the Secretary's conduct does not "shock the conscience" and thus the

⁸ This ruling is as to the original overpayment calculation. Maxxim's due process claim regarding the recalculation under § 3.10.9.2 ordered by the MAC will be addressed in section D below.

Secretary is entitled to summary judgment on Maxxim's substantive due process claim.

D. The Recalculation

Having ruled that the ALJ erred in setting aside the overpayment extrapolation, the MAC ruled that the overpayment must be recalculated based on the ALJ's unchallenged decision that 25 of the 30 sample claims (as opposed to all 30 as determined by TriCenturion) were incorrect.

The MAC's ruling was based on PIM § 3.10.9.2, which provides:

If the decision on appeal upholds the sampling methodology but reverses one or more of the revised initial claim determinations, the estimate of overpayment shall be recomputed and a revised projection of overpayment issued.

Maxxim contends that the recalculation order violates its right to due process because there is no mechanism for further appeal. Yet, 42 C.F.R. § 405.980 provides that a matter may be reopened at any time to correct mathematical or calculation errors. Maxxim has not explained or offered any authority for its contention that it would have no remedy if the calculation were performed in error. In addition, Maxxim's concern is purely speculative; the recalculation may well be accurate.

E. Declaratory Judgment

Because the court concludes that substantial evidence supports the Secretary's

decision, and Maxxim has not met its burden to show a due process violation, Maxxim's requests for declaratory judgment that the overpayment is invalid and PIM § 3.10.9.2 is unconstitutional are denied.

Conclusion

For the reasons set forth above, Maxxim's motion for summary judgment is denied, the Secretary's motion for summary judgment is granted, and this case is remanded to the PSC for the recalculation ordered by the MAC decision.

Signed at Houston, Texas on November 29, 2011.



Stephen Wm Smith
United States Magistrate Judge